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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/574,626

05/19/00

REMACLE

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EXAMINER

ZHOU, S

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

02/22/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/574,626

Applicant(s)

REMACLE ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 14

- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

#### ***Specification***

The abstract of the disclosure is objected to because it is not a single paragraph. Correction is required. See MPEP § 608.01(b).

The specification is objected to also because the Brief Description of the Drawing section fails to describe each and every figures disclosed.

#### ***Claim Rejections-35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "almost symmetrically" of claim 22 is vague and indefinite since it is not clear at what angle(s) would be "almost symmetrically".

#### ***Claim Rejections-35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 23 is drawn to a computer program, which is interpreted as descriptive material. Although a computer program could be functional descriptive material, it is non-statutory subject matter when claimed as descriptive material *per se*. See MPEP 2106 section IV(B)(1).

***Claim Rejections-35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abouzied et al. (Journal of AOAC International, Vol. 77, No. 2 (MAR-APR), pp. 495-501, 1994) in view of Howard III et al. (IDS document: EP 0646784A1, 05-04-95), and in further view of Roth et al. (US patent # 5,902,727, Issued May 11, 1999, application filing date: Sep. 4, 1996) and Terstappen et al. (US patent # 5,646,001, July 8, 1997).

Abouzied et al. disclose a method of simultaneously screening and detection of multianalyte using membrane strips (interpreted as the array of the instant claims) as summarized in the abstract, comprising the steps of contacting analytes (interpreted as the target compounds in the instant claims), with multiple antibodies (interpreted as the capture molecules of the instant claims) to let them bind; precipitation being formed on the membrane upon binding; detection and quantification of the precipitates by light reflection and video image analysis. The binding as disclosed is a reaction between an antigenic structure and its corresponding antibody as is required in the instant claims and the antibody and its corresponding antigen can be interpreted at a broad sense, as a receptor and its corresponding ligand, as required of the instant claims. The presence of the precipitates is detected by both visual detection of the color intensity by reflection, as required in the instant claims, and for quantification, image is taken by a CCD video camera and is converted into digital form (abstract and Experimental, pages 495-497). Abouzied also disclosed an apparatus, termed "a computer-assisted multianalyte assay system", for the detection and/or quantification of multianalytes, which apparatus comprises detection and/or quantification device including camera, and a computer to collect results including the images taken by the camera, as required in the instant claims (Figure 1 and page 497). A video-digitizing board is equipped with the CCD camera and is interpreted as the sensor as required in the instant claims. A computer

program for performing the above steps is stored on a computer readable medium, which is in the broad sense the printed paper copy of the publication.

Abouzied et al. does not disclose but suggest and motivate the use of a strip of at least 20 discrete regions per  $\text{cm}^2$  for analyzing not only antigen-antibody, but also hybridization of two nucleotide sequences and other analytes by stating that this "should be applicable to the simultaneous screening of multiple mycotoxins and other agricultural residues in food" (see abstract). Throughout the reference including the title, abstract and conclusion, Abouzied et al. mention numerous times the assay for "multianalytes", which obviously motivates practices of the method for the detection of multiple analytes including 2, 10, 20, or 30. Although it appears from the reference that the dimension of the line blots disclosed does not allow a density of 20 or more discrete regions per  $\text{cm}^2$  with each region having one species of capture molecule, as stated above, Abouzied et al. motivates the use of blots with high density of discrete regions by using different supporting medium and/or different means of applying molecules onto the medium such as a glass surface and/or application of molecules with a pin in order to assay for multiple analytes.

Brown et al. disclose an invention including a substrate with a surface having a microarray of at least 10 distinct polynucleotide or polypeptide biopolymers in a surface area of less than about 1  $\text{cm}^2$  (see column 4, lines 16-23).

Howard III et al. disclose apparatus and methods of using video test strip reader to analyze analytes. The apparatus disclosed comprises CCD camera equipped with illumination sources and computer system (see page 5). The apparatus also comprises an image handler coupled to the video imager and a video reader. The video handler includes a signal converter that converts or digitizes the analog signal from the video imager into a digital signal representing the image (see the paragraph bridging pages 5

and 6 and paragraph 2 of page 6). The imager handler, video imager, and the video reader are interpreted as the "sensor(s) provided with camera(s)" as required in the instant claims. The signal converter (page 11, line 3) is also interpreted as such sensor. Howard III et al.'s apparatus can also evaluate information such as bar code as required in the instant claims (see page 7, lines 55-56). The apparatus disclosed uses its processor to initially calibrate and produce reflectance reference matrices by reading the reflectance value for the viewing field, i.e. the first reference standard as required in the instant invention, and measure the reflectance for that test area in addition to the test pad, i.e. the second reference standard in the instant invention. Howard III et al. do not disclose but motivate the use of more than one illuminant sources specially arranged, spaced and controlled, as required in the instant claims, in order to "evenly illuminate the viewing field...in order for video imager...to accurately measure the color or reflectance of the various test pads" and "the illumination source is preferably a DC light source with a control feedback to minimize light fluctuations" (see page 5, lines 51-55) and the motivation is witnessed further by the phrase "any illumination variations on the viewing area" (page 11, line 20). Howard III et al. also suggest the use of other light sources including infra-red light, as required in the instant claims (see page 7, lines 5-10).

Abouzied et al. and Howard III et al. do not disclose using multiple cameras in the system as required in the instant claims. However, it would be obvious to ordinary people in the art to use more than one camera to simply expedite the performing process. They also do not disclose the detection of the presence of the precipitate by using metallic compound, magnetic metallic compound, the reduction of silver in the presence of colloidal gold particles, etc., as required in the instant claims. However, these are common means used in different assays in the prior arts as summarized in

Roth et al.: "the binding of such probes to the target substance is typically detected microscopically by the use of direct labeled probes such as fluorophores, enzyme conjugates, gold particles and the like" and "recent advances in detection systems have improved the sensitivity and resolution of the probe localization and include such methods as immunogold with silver intensification, peroxidase-anti-peroxidase..." (see column 1). Terstappen et al. also summarize the use of metallic and magnetic metallic compounds in biochemical separation and detection (see the bridging paragraph between columns 2 and 3). Thus, it would be obvious for one to combine these techniques with the teachings of Abouzied et al. and Howard III et al. to practice the detection of precipitates with these techniques as required in the instant claims.

In summary, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the teachings and/or motivations of Abouzied et al., Howard III et al., Roth et al., and Terstappen et al. to practice the claimed methods using the claimed apparatus in identification and/or quantification of a target compound obtained from a biological sample.

### ***Conclusion***

No claim is allowed.

Enclosed please find among other things a copy of the PTO-1449 with one reference lined through because the reference is in German and the Examiner does not read German. If applicants wish consideration of the reference, a certified translation of the reference has to be provided to the Examiner.



Art Unit: 1631

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:


Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou: sjz  
Patent Examiner  
February 6, 2001



  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER